MEDICAL DEVICE REGULATION AND ITS COMPARISON IN EUROPE, AUSTRALIA AND INDIA

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ABSTRACT

 Millions of patient’s world widely depends on ever widening arrays of medical devices for the diagnosis, treatment and prevention and management of diseases. In Europe medical devices are regulated by European Commission and covered under New Approach of Directives. In Australia medical devices are regulated by Therapeutic Goods Administration (TGA) and in India it is regulated by central drugs standard control organizations (CDSCO). All these countries have slight different classification system and registration process for classifying and registering the medical devices in respected countries. This article mainly includes classification, registration process for approval, labeling requirements, adverse drug reaction reporting system and registration requirement for approval of medical devices in these three countries. This type of evaluation is helpful for newly developing industries for better understanding of all requirements as a regulatory point of view. Time duration limit for review of medical device registration fixed in Australia divergence to India regulation. Medical device registered for five year as per European and Australian regulation whereas in India only for three year. Application fees for registration of medical device in Australia and Europe seen costly as compared to Indian application fees.

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INTRODUCTION

Medical device is any instrument, implant, in vitro reagent, apparatus or similar or any related article which are used for diagnosis, prevention, or treatment of disease or any other conditions, and which does not achieve its purposes through chemical action within or on the body \[^1\]. Medical devices are becoming more important in the health care sector. This increases the demand for better regulatory frameworks to ensure that products entering the market are safe and efficient. One of the major issues for companies developing and producing medical devices is to be updated on the regulatory requirements and implement them in the process. A company that does not succeed with this may lose thousands of dollars in the delay of marketing the product. The Australian medical devices and diagnostics market was worth $2.9 billion in 2009 and is estimated to grow to $4.3 billion in 2013 at a compound annual growth rate of 10.3%. The global medical device market is worth over US$150 billion, with the United States of America, European Union, and Japan having over 65% of the market share.

Regulation of Medical Device, according to the Europe:

In Europe Medical Devices are regulated by European Commission. In European Union, European Medicines Agency (EMA) is a decentralized agency which is located in London. EMA is mainly responsible for scientific evaluation of medicines which are developed by pharmaceutical companies for use of it in the European Union \[^2\]. The European Medicines Agency’s (EMA) is also responsible for the protection and promotion of public and animal health, by the supervision and evaluation of medicines for human and veterinary use.

Definition:

Medical devices are any instrument, appliance, apparatus, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes and for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- Diagnosis, monitoring, prevention, treatment or alleviation of any disease,
- Diagnosis, treatment, monitoring, alleviation or compensation for an injury or handicap,
- Replacement, Investigation or modification of the anatomy or of a physiological process,
- Control of conception, which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means \[^2\].

Classification:

Depending on the level of risk medical devices are classified in to four categories as Class I, Class II, Class III and Class IV \[^3\].

<table>
<thead>
<tr>
<th>Classification</th>
<th>Risk Level</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Low risk</td>
<td>Stethoscope, Conductive Gels</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Medium risk</td>
<td>Antistatic Tubing For Anaesthesia</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Elevated risk</td>
<td>Ventilators, Infusion Pumps, Anaesthetic vaporizers</td>
</tr>
<tr>
<td>Class III</td>
<td>High risk</td>
<td>Implants and dressings made from collagen, Biological Heart valves</td>
</tr>
</tbody>
</table>

Regulation:

European Medicines Agency (EMA) is a decentralized body of the European Union (EU) which is responsible to protect human and animal health through the supervision and evaluation of medical products for human or animal use \[^2,3\].

There are main three directives for medical devices:
- Active Implantable Medical Device (AIMD) Directive - 90/385/EEC
- Medical Device Directive (MDD) - 93/42/EEC
- In Vitro Diagnostic Device Directive (IVD) - 98/79/EC

Other Directives:
- Machinery Directive – 98/37/EC
Placing medical devices on the market:

According to EMA, market approval for medical devices is achieved via a decentralized procedure of CE marking\(^2\,^4\,^5\). If any manufacturer wants to sell medical devices in the EU, there is a need of only submitting one single marketing authorization application to the EMEA. The documentation shall be in English, French or German. A manufacturer who does not have a registered place of business in the EU shall appoint a single authorized representative in the European Union\(^2\,^3\,^4\).

The devices shall have a GMDN code. All medical devices except class I medical devices require the involvement of a Notified Body. Medical devices must comply with the essential requirements of Annexure I of the Directive 93/42/EEC\(^2\,^4\,^5\). Harmonized Standards are used to meet compliance with the essential requirements. Clinical trials are required for Active Implantable Medical Devices, Invasive Medical Devices, class III devices and for long-term use of class Ila and Iib medical devices. For class I and Ila devices instructions for use are not necessary if they can be used safely without them. A registration of a product is valid for 3 years.

The European market approval system consists of national authorities for separate registration and certification of medical devices. The decentralized procedure mainly depends on the designated notified bodies that regulate CE marking.

Regulatory process for approval of Medical Device\(^6\):

CE-Marking:

CE mark is a conformity mark, which must place on all European medical devices before they can be marketed. It is a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation including those related to safety and quality\(^2\,^3\). The CE mark also means that the product can be freely marketed anywhere in the European Economic Area (EEA) without further control\(^2\).

Competent Authorities (CA), Notified Bodies (NB) and authorized representatives are involved in the CE marking process. Competent Authorities are exists in each European Member State and are nominated by each government to monitor and ensure compliance with its provisions of the MDD\(^2\,^5\). The Competent Authority designates a Notified Body to ensure that conformity assessment procedures are completed according to the relevant requirements. The Authorized Representative is designated by the manufacturers and they are legally responsible for compliance with the regulations of medical device directives. Manufacturer of the medical devices are responsible to ensure that their product complies with the essential requirements of the relevant EU legislation.

CE-certification includes the following steps:

- Decision whether or not a product is a medical device
- Medical Device classification by the manufacturer
- Contact to Notified Bodies, preliminary discussions and answering of specific questions, confirmation of device classification by the Notified Body
- Time and cost estimation for different certification routes
- Formal application and certification contract
- Submission of documents to the Notified Body
- Evaluation of the submitted documents and report
- Audit of the manufacturer’s operations if applicable
- Decision about the certification and issuing of the relevant certificate
- Surveillance audits, Full re-audit and issuing of a new certificate (usually after five years)
A CE mark expires after three years. Upon CE certification in the first year, unannounced surveillance audits follow. As part of vigilance, the safety and intended use of the medical device is monitored after its introduction on the market post-marketing surveillance (PMS) and post-marketing clinical follow-up (PMCFU). In the fourth year, renewal of the CE mark can be applied \(^{[2-4]}\).

The manufacturer or the authorized representative is requested to keep copies of the technical documentation at least 5 years for IVDs and at least 10 and 15 years for AIMDs, after the last product has been placed on the market.

**Notified Bodies:**

For the conformity assessment of certain products the European new approach directives require the involvement of third parties and these are the national authorities of the member states \(^{[2,4]}\). Under surveillance by national notifying authorities Notified Bodies have the authority to withdraw or modify the notification as soon as the conditions of notification are no longer met.

Notified Bodies are free to offer their conformity assessment services for which they are notified to any manufacturer established either inside the EU or in third countries. They may carry out these activities on the territory of other countries either with their own personnel or with subcontractors.

**Quality Systems:**

Effective quality management systems (QMS) are key regulatory consideration for allowing permitting medical device manufacturers to market their products around the world. ISO 13485 is a harmonized standard for the quality management system requirements for medical device manufacturers.

The Medical Device Directive requires that the manufacturers of medical devices keep a product-related, efficacious and adequate quality system. The application of the quality system must ensure that the products comply with the provisions of the MDD \(^{[2,3]}\). All the requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic manner in the form of written policies and procedures such as quality plans, quality manuals, quality programs and quality records \(^{[2]}\).

Additional aspects to be covered by the quality management system include:
- The technical documentation.
- Reference to the essential requirements according to Annex I of the Medical Device Directive.
- Information about medical device regulations and harmonized standards.
- Instructions for use and Labeling.
- Risk Analysis
- Different languages used
- Post-marketing surveillance (PMS)
- Reporting of ADR under the vigilance system
- Retention of certain documents

Depending on the class, status of QMS and the technical file cost and duration of the certification procedure itself are varied. The minimum duration of a certification procedure with a Notified Body is twelve weeks.

**Documents required:**

- Name and address of manufacturer and identification of products
- European Agents name and address if applicable
- WHO-GMP compliance certificate
- Declaration of Conformity and/or certificate for regulated product
- Description of product (Name, Type, Model)
- Test reports
- Technical File

**Labeling Requirements:**

Each device must be accompanied by the information needed to use it safely and properly by which users can understand it easily and also be identified by the manufacturer. This information comprises all the details of the product i.e. instructions for use, intended purpose and storage condition of the product.

Instructions for use must be included in the packaging for every device. Except Class I or Class IIa devices there is no need such instructions for use, if they can be used safely without any such instructions.

Where appropriate, this information should also include specific form of symbols or identification color. It is necessary to conform that any identification color or symbol used are complies with the harmonized standards. In such where no standards exist, the symbols and colors used must be described in the documentation supplied with the device.
The label may bear following requirements:\(^6\):
- Name, address and trade name of the manufacturer
- Address of the manufacturing site
- Name and address of the authorized representative (if the manufacturer does not have a registered place of business in the Community)
- Details to identify the device and the contents of the packaging especially for the users
- If medical device is sterile than use the word “STERILE”
- If medical device is used for single use than indicate it as “SINGLE USE”
- If any device is custom-made, than use the word “custom-made device”
- If any device is intended for clinical investigation than use the word “exclusively for clinical investigations”
- Batch code preceded by the word “LOT”, or the serial number;
- If appropriate any special storage or handling conditions;
- If appropriate any special operating instructions;
- Any warnings and precautions to take, if required;
- If applicable give method of sterilization;
- Manufacturer clearly states the instruction for use on the label (with its intended purpose, any undesirable side-effects and contraindication);
- If medical device is reusable, give information about the appropriate processes to allow reuse;
- Any devices which emit radiations used as medical purposes than give the details of the nature, type, intensity and distribution of this radiation.

Vigilance system:
- The main purpose of the Vigilance system is to protection of health and safety of patients, users and others by reducing the adverse incident being repeated in different places at different times. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.
- The response of the vigilance and market recall is to determine the action to be taken once we receive information concerning an incident directly or if the Competent Authority receives it) after the device has been placed in the market.
- Time scale for initial reporting is as follows: Serious public health threat – immediately, not later than 2 days Death or unanticipated serious deterioration in state of health - not later than 30 elapsed calendar days.

Medical device regulatory system in Australia:
In Australia medical devices are regulated by TGA (Therapeutic Goods Administration). The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, which are responsible for regulating medicines and medical devices. According to the Therapeutic Goods 1989 Act, therapeutic goods (medicines and medical devices) supplied in Australia must meet acceptable standards of safety, efficacy, quality and performance. On the basis of clinical and scientific expertise to decision-making, TGA ensures any risk associated with the use of medicines and medical devices. The TGA depends on the healthcare professionals, public and industries to report problems with medicines or medical devices. TGA investigate the received reports and determine any necessary regulatory action\(^7\).

Definition:
On the basis of Therapeutic Goods Act 1989, medical devices are defined as\(^7\):
- “Any appliance, instrument, apparatus, material or other article (whether used in combination or alone, and including the software necessary for its proper application) intended by the person under whose name it is to be supplied, to be used for human beings for the purposes of one or more of the following:
  - Diagnosis, treatment, monitoring, prevention or alleviation of disease,
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - Modification, Investigation or replacement of the anatomy or of a physiological process,
  - Control of conception, and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; or an accessory to such an instrument, apparatus, appliance, material or other article.”

Classification of medical device as per Australia:
Based on the level of risk and the intended purpose of the Medical Device, they are classified in to 5 classes in accordance to a set of 22 classification rules. The higher the class, the more regulatory control is required\(^7, 8\). Depending on the level of risk, medical devices are classified as following:
Table 2: Classification of Medical Device as per Australia\textsuperscript{[7, 8]}

<table>
<thead>
<tr>
<th>Classification</th>
<th>Risk level</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Low risk</td>
<td>Urine Collection Bottle, Non-sterile Dressings, Plaster Bandages, Handheld dental mirrors, Scissors, Surgical microscopes, Anesthesia Breathing Circuits, Intravenous tubing, Blood transfusion sets, Adhesive for topical use,</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Low-Medium risk</td>
<td>Contact lenses, Nasopharyngeal airways, Oxygen Tubing and Mask, Suturing needles and Clamps</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Medium-High risk</td>
<td>Artificial Eyes, Dressing for Chronic Extensive Ulcerated Wounds, Condoms and Nebulizers, Personal insulin injectors, Bone cements, Lung ventilators, Antibiotic bone cements,</td>
</tr>
<tr>
<td>Class III</td>
<td>High risk</td>
<td>Cardiovascular Catheter, Prosthetic Heart valves, Cardiac Output Probes</td>
</tr>
<tr>
<td>AIMD (Active Implantable Medical Device)</td>
<td></td>
<td>Cardiac stents, Pacemaker, Nerve stimulator, Cardiac defibrillator</td>
</tr>
</tbody>
</table>

Registration of medical device as per Australia:

The sponsor is responsible for registration of the medical devices in the Australian Register of Therapeutic Goods (ARTG) database. Before registration of the medical devices in the ARTG, the medical device must be classified according to the Australian system and suitable risk analysis has been done and quality management systems (QMS) must be applied for complying with the Essential principles according to required criteria\textsuperscript{[7]}. Sponsor may use the Devices Electronic Application Lodgment system (DEAL system) for the applications and registering of medical devices. Sponsors are responsible for all activities concerning medical devices while manufacturers have obligations to fulfill the requirements. After registration medical devices have Global Medical Device Nomenclature (GMDN) codes\textsuperscript{[7]}.

A quality management system (QMS) is required for medical devices class IIa, IIb, III and AIMDs to get a conformity assessment certificate. Australia has its own standard orders but the international ISO standards can be used. According to the Australian Essential principles which ensure the safety and efficacy of the therapeutic goods, manufacturer is required to have made a documented risk analysis of the product. For Class III medical devices and AIMDs conformity assessment certificate is required and manufacturer shall submit a Design Dossier whereas for class I medical devices conformity assessment certificate is not required. The registration of medical device is valid for five years\textsuperscript{[7]}.

Figure 2: Registration process of medical device in Australia\textsuperscript{[7]}
Documents required\(^7\):  
- Name and Address of Manufacturer and there relevant details  
- All the details of Client  
- Conformity assessment certification including the certificates details and if there are any restrictions on the scope  
- Classification and classification rule of the device  
- Conformity assessment procedure  
- Conformity assessment body  
- GMDN code - The Global Medical Device Nomenclature (GMDN) code is a collection of terms, each with a unique code number, to describe and catalogue medical devices.  
- Australian declaration of certificate

Labeling Requirements\(^7\):  
- Name of Therapeutic device  
- Name and address of manufacturer and sponsor or Registered trademark of manufacturer or sponsor of therapeutic devices  
- Instruction for use  
- Batch number and serial number preceded by words “Batch”, “Batch Number”, “Batch No.”, “Lot”, “Lot Number”, “Lot No.” or “Lot Code”, “Serial Number”, “Serial No.”, or by words having a similar meaning, or by the symbol “B”, “(B)”, or “B “, “SN”, “S/N”, or “FABR”.  
- Date of manufacture may be used as the “batch number or serial number” (if clearly identifiable as a date).  
- If any devices used in examination of specimens taken from the body of a person or animal in connection with the diagnosis of a disease, injury or any defect than preceded as “diagnostic goods for in vitro use”.  
- Package containing one or more therapeutic devices, means the outermost level of packaging on that number of therapeutic devices which is supplied for use is preceded as “Outer package”.  
- Size describes the size or shape of device and may include:  
  - physical measurement of device  
  - Descriptive expression including: “small”, “medium” or “large”.  
- If any medical device is sterile than represented as “sterile therapeutic device”.  
- If medical devices are used in one occasion only than preceded as “single use” or “use only once”.  

Vigilance system:  
The purpose of medical device vigilance is to protect the health and safety of patients, users, and others by reducing the adverse events being repeated. This can be achieved by:  
- Evaluating reported adverse incidents  
- Disseminating information that could be used to prevent or minimize the consequences of adverse events, where appropriate  
- Modifying the therapeutic goods (Medicines and medical devices)  
- Removing the medical device from the market\(^7, 8\)  
  Action is undertaken by the TGA and the sponsor or manufacturer may aware of information about medical devices which are supplied in Australia, such as:  
- Malfunctions  
- Adverse event reports  
- Results of testing and any other information  
  Manufacturer, sponsor and user may responsible for reporting adverse drug reaction of medical devices. Implantable medical device tracking system (IMDTS) is tracking system for ADR reporting. Manufacturer may report death and serious injury within 10 days, non-adverse event or event not result in death or serious injury within 30 calendar days (1 month) and any serious public health threats require prompt remedial action within in 48 hours (2 days)\(^9\).  

Medical Device Regulatory system in India:  
In India medical devices are regulated by Central Drugs Standard Control Organization (CDSCO)\(^10\). The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has six zonal offices, four sub-zonal offices, 11 port offices and six laboratories under its control\(^10\). In India medical devices are regulated by Directorate General of India (DCGI), Ministry of Health and Family Welfare (MHW)\(^10, 11\). In India Drug Technical Advisory Board (DTAB) has recommended strict implementation of Indian Conformity Assessment Certificate (ICAC) for manufacture, import and marketing the medical devices on Indian market\(^11\). Indian Medical Device Regulatory Act (IMRDA) had been set up for their opinion and recommendation\(^11\). The importing, manufacturing, distribution and sale of medical devices in India are overseen by drug and cosmetic act (1940) and rules (1945) and Inspections are carried out by CDSCO.
Definition:
Medical devices are any apparatus, instrument, implant or other similar or related article, which are intended for use in diagnosis, disease, cure, mitigation, prevention or treatment of disease or intended to affect the structure or any function of the body and which does not achieve its primary intended purposes through its chemical action within or on the body \[10\].

Classification of medical devices as per India:
Depending on the level of risk medical devices are classified in 4 categories in to Class A, Class B, Class C and Class D \[10\].

<table>
<thead>
<tr>
<th>Classification</th>
<th>Risk level</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class A</td>
<td>Low risk</td>
<td>Tongue Depressors, Thermometers</td>
</tr>
<tr>
<td>Class B</td>
<td>Low-Moderate risk</td>
<td>Suction Equipment, Hypodermic Needles</td>
</tr>
<tr>
<td>Class C</td>
<td>Moderate-High risk</td>
<td>Lung ventilator, Bone Fixation Plate</td>
</tr>
<tr>
<td>Class D</td>
<td>High risk</td>
<td>Pacemaker, Heart valves, Implantable Defibrillator</td>
</tr>
</tbody>
</table>

Registration procedure of medical device as per India:
New medical Devices and Notified Medical Devices are classified under drug rules which require marketing Authorization from DCGI. Other medical devices such as Non-notified medical devices do not require manufacturing, sales, import registration and can be marketed freely \[10\]. The applicant can be the manufacturer, the importer or the responsible agent in India \[10, 11\]. The registrations of medical devices are done according to Rule 24A of the Drugs and Cosmetic Act and Form 40 shall be filed. Manufacturers of medical devices conduct suitable tests to prove the product quality and quality systems shall concern design, development and manufacture. If quality systems for medical devices do not exist, CE-marked or FDA approved products are preferred because of their quality, performance and safety. Medical devices also require risk management in form of ISO 14971.

Manufacturer or authorized agent of medical devices shall have documented procedures for distribution records, complaint handling, adverse incident reporting and product recall. A registration of a medical device is valid for five years \[11\].

Documents required \[12\]:
- Covering Latter
- Authorization latter
- TR6 (Treasury) challan
- Power of Attorney
- Free Sale Certificate
- Name and Address of Manufacturer
- Name and Address of Authorized Agent
- Declaration of certificate
- Wholesale License
Labeling Requirements:\(^{13}\):
- Product description
- Name of manufacturer or authorized representative
- Address of premises
- Number of units of content
- Batch number preceded by words “Batch No”, “B. NO.”, “Batch” or “Lot No.”
- Manufacturing license number preceded by word “Manufacturing License Number” or “Mfg. Lic. No.” or “M.L.”
- Date of expiration

Vigilance system:
Manufacturer is responsible for reporting adverse drug reaction of any medical devices. There is no specific tracking system for reporting of adverse drug reaction of medical device. Manufacturer may report death or serious injury or a serious public health threat within 10 calendar days and other reportable event not later than 30 calendar days.

Comparison of medical device regulation in Europe, Australia and India:

### Table 4: Comparison of medical device regulation in Europe, Australia and India.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Europe</th>
<th>Australia</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Authority</td>
<td>• European Commission</td>
<td>Therapeutic Goods Administration (TGA)</td>
<td>• Central Drugs Standard Control Organization (CDSCO)</td>
</tr>
<tr>
<td></td>
<td>• European Medicines Agency (EMA)</td>
<td></td>
<td>• CLAA is a main regulatory body for medical device</td>
</tr>
<tr>
<td>Legislation and guideline follows</td>
<td>3 Directives:</td>
<td></td>
<td>• By CDSCO</td>
</tr>
<tr>
<td></td>
<td>• Active Implantable Medical Device (AIMD) Directive - 90/385/EEC</td>
<td>• Australian Regulatory Guideline for Medical Devices (ARGMD)</td>
<td>• Directorate General of Health of India (DCGI), Ministry of Health and Family Welfare Gov. of India</td>
</tr>
<tr>
<td></td>
<td>• Medical Device Directive (MDD) - 93/42/EEC</td>
<td>• TGA 1989 Act</td>
<td>• IMRDA (Indian Medical Device Regulatory Act)</td>
</tr>
<tr>
<td></td>
<td>• In Vitro Diagnostic Device Directive (IVD) - 98/79/EC</td>
<td>• TGA Regulation 2002</td>
<td>• Drug and Cosmetic Act (1940) and rules (1945)</td>
</tr>
<tr>
<td>Classification</td>
<td>4 categories depends on level of risk:</td>
<td>5 categories depends on level of risk:</td>
<td>4 Categories depends on level of risk:</td>
</tr>
<tr>
<td></td>
<td>Class I - Low Risk</td>
<td>Class I - Low Risk</td>
<td>Class A - Low Risk</td>
</tr>
<tr>
<td></td>
<td>Class IIa - Medium Risk</td>
<td>Class IIa - Low to medium Risk</td>
<td>Class B - Low to medium Risk</td>
</tr>
<tr>
<td></td>
<td>Class IIb - Elevated Risk</td>
<td>Class IIb - Medium to high Risk</td>
<td>Class C - Medium to high Risk</td>
</tr>
<tr>
<td></td>
<td>Class III - High Risk</td>
<td>Class III - High Risk</td>
<td>Class D - High Risk</td>
</tr>
<tr>
<td>Rules</td>
<td>Total 18 rules</td>
<td>Total 22 rules</td>
<td>Not specified</td>
</tr>
<tr>
<td>Essential Principles Applicant</td>
<td>Compulsory</td>
<td>Compulsory</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Applicant</td>
<td>Manufacturer/Authorized representative</td>
<td>Manufacturer/Australian based sponsor/Agent on behalf of Manufacturer and sponsor</td>
<td>Manufacturer/Authorized representative</td>
</tr>
<tr>
<td>Application in form of Documents Required</td>
<td>Technical file</td>
<td>Technical file</td>
<td>Technical file</td>
</tr>
<tr>
<td></td>
<td>• Name and address of manufacturer and identification of products</td>
<td>• Manufacturer’s details including name and address</td>
<td>• Covering Letter</td>
</tr>
<tr>
<td></td>
<td>• European Agents name and address if applicable</td>
<td>• Client reference and details</td>
<td>• Authorization letter</td>
</tr>
<tr>
<td></td>
<td>• WHO-GMP compliance certificate</td>
<td>• Conformity assessment certification including the certificates details and if there are any restrictions on the scope</td>
<td>• TR6 challan</td>
</tr>
<tr>
<td></td>
<td>• Declaration of Conformity and/or certificate for</td>
<td>• Class of the device</td>
<td>• Power of Attorney</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Conformity assessment procedure</td>
<td>• Free Sale Certificate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Manufacturer’s detail</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Declaration of certificate</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Wholesale License</td>
</tr>
</tbody>
</table>
regulated product
- Description of product (Name, Type, Model)
- Test reports
- Technical File

Conformity assessment body
- GMDN code - The Global Medical Device Nomenclature (GMDN) code is a collection of terms, each with a unique code number, to describe and catalogue medical devices
- Australian declaration of certificate

Indicative mark required
- CE mark
- ARTG number
- CE mark – TGA refers CE mark as EC- European community certificate
- ICAC marking – Indian Conformity Assessment Certificate
- CE mark and FDA approval is required

Registration steps
Step 1 - Confirm classification of the device
Step 2 - Authorized representative and notified bodies are appointed
Step 3 - Submission of documents and Evaluation of documents
Step 4 – Provide CE certification
Step 1-Manufacturer obtain conformity assessment certificate from TGA and gives to the sponsor.
Step 2 – Sponsor submits the application in to DEAL system with appropriate charges.
Step 3 - TGA review and accepts the application
Step 4 – TGA includes the device in ARTG.
Five years

Registration done for Fees
- Certification Fees charged by Notified Body.
- Official fees charged by government competent authorities.
- In UK registration and notification fees are about 133 US$
- In Spain registration and notification fees are about 705 US$
- Class I measuring – 0 AUD$
- Class I sterile - 730.00 AUD$
- Class IIa - 730.00 AUD$
- Class IIb - 730.00 AUD$
- Class III - 960.00 AUD$
- AIMD - 960.00 AUD$
- Class IIa - 730.00 AUD$
- Class IIb - 730.00 AUD$
- Class III - 960.00 AUD$

Conformity Assessment
- Compulsory – performed by Authorized Notified Body
- Compulsory
Prepared by authorized notified body and manufacturer and sponsor

Post market surveillance activity
- ADR reporting
- Field safety notice
- Investigation enforcement
- Post market clinical follow-up records
- ADR reporting
- Vigilance exchange program
- Enforcement activities
- Distribution record
- Audits

Vigilance system
ADR reporting by
Adverse Incident Tracking System (AITS)
Manufacturer/Authorized representative/Competent authority
- Implantable Medical Device Tracking System (IMDTS)
Manufacturer/Sponsor/User

Fees
- Fees paid through TR6 (Treasury) challan or through electronic clearance system (ECS)
- Registration fees – 1500 US$
- For registration of single product – 1000 US$
- For additional products - 1000 US$
- For duplicate copy – 300 US$
- For class A – performed by manufacturer
- For other class by Authorized Notified Body
- ADR for importers
- Complaint handling ADR reporting procedure for distribution of records
- Recall procedure
- No tracking system
- Manufacturer
CONCLUSION

Medical devices are serving an increasing role in improving patient’s health and quality of life and in clinical practice. All three countries follow the GHTF regulations for medical devices but all have their own guidelines. All the three countries have different regulatory approval process for registration of medical device. By comparing all the parameters it has been seen that Europe and Australia has more stringent regulations as compared to India and according to the application fees Australian registration fees are most costly as compared to all the three countries. Medical devices cover a vast range of equipment, from simple tongue depressors to haemodialysis machines. Like medicines and other health technologies, they are essential for patient care – at the bedside, at the rural health clinic or at the large, specialized hospital. Surprisingly, regulatory controls for medical devices are scarce in the developing world, even though implementation of national medical device regulations will often address the very issues raised in countries as major concerns for patient safety. As an important input to the health care system, medical devices should be properly managed and utilized in order to produce an efficient health intervention.

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ABBREVIATION

TGA: Therapeutic Goods Administration
CDSCO: Central Drugs Standard Control Organization
EMA: European Medicines Agency
EU: European Union
AIMD: Active Implantable Medical Device
MDD: Medical Device Directive
IVD: In Vitro Diagnostic Device Directive
ARGMD: Australian Regulatory Guideline for Medical Devices
EC: European Commission
GMDN: Global Medical Device Nomenclature
ISO: Indian Standard Organization
EEA: European Economic Area
CA: Competent Authority
NB: Notified Body
PMS: post-marketing surveillance
PMCFU: Post-marketing clinical follow-up
QMS: Quality Management System
DEAL System: Device Electronic Application Lodgment
IMDTS: Implantable Medical Device Tracking System
ADR: Adverse Drug Reaction
ICAC: Indian Conformity Assessment Certificate
IMRDA: Indian Medical Device Regulatory Act
DCGI: Directorate General of Health of India

REFERENCES